UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

FWK Holdings, L.L.C., on behalf of itself and all others similarly situated, Plaintiff, v. LANNETT COMPANY, INC., MYLAN PHARMACEUTICALS INC., SANDOZ, INC., and NOVARTIS AG, Defendants.	Civil Action No. 16-cv-9900 **JURY TRIAL DEMANDED**

DIRECT PURCHASER CLASS ACTION COMPLAINT

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Plaintiff FWK Holdings, L.L.C. ("Plaintiff"), on behalf of itself and all others similarly situated, against Defendants: 1) Lannett Company, Inc. ("Lannett"); 2) Mylan Pharmaceuticals, Inc. ("Mylan"); and 3) Sandoz, Inc. and Novartis AG (defined below collectively as "Sandoz"), (collectively, the "Defendants"), alleges:

I. INTRODUCTION

1. This is a civil antitrust action seeking treble damages arising out of the Defendants' unlawful scheme to fix, maintain, and stabilize the prices of generic levothyroxine ("Levothyroxine").

2. Levothyroxine is a manufactured thyroid hormone that is the synthetic equivalent of the hormone thyroxine. First manufactured in 1927, Levothyroxine is used primarily to treat thyroid hormone deficiency, or hypothyroidism. Levothyroxine is on the World Health Organization's list of essential medicines, and patients who take it often need it for their lifetimes. In recent years it has repeatedly been featured on lists of the top ten most prescribed generic drugs, and as of June 2015, it was the most prescribed generic drug in the U.S. and constituted 2.7% of the entire generic drug market by number of prescriptions.

3. As alleged below, Defendants' scheme injured Plaintiff and the Class of direct purchasers it seeks to represent (as defined below), causing them to pay overcharges. Plaintiff seeks to recover these overcharges and seeks other relief arising out of Defendants' conspiracy to charge supra-competitive prices for Levothyroxine during the period from November 21, 2013 to the present ("Class Period").

4. Beginning in November 2013, as set forth hereafter, contrary to past practice, Defendants caused the price of Levothyroxine to dramatically increase in unison by more than 200%. The increases were the result of an agreement among Defendants to increase pricing and

restrain competition for the sale of Levothyroxine in the United States. The agreement was furthered by discussions at meetings held at Generic Pharmaceutical Association ("GPhA") meetings, including a meeting in Bethesda, Maryland in October 2013.

5. Defendants Lannett, Mylan and Sandoz sold Levothyroxine during the Class Period. Following the October 2013 meeting, Defendants Lannett, Mylan and Sandoz collusively raised prices of Levothyroxine by a material amount. Prior to November 2013, the average amount in the U.S. paid for Levothyroxine was stable. Within a few weeks of the October 2013 meeting, the average prices for Levothyroxine began to increase by extraordinary amounts. Each of the twelve different available dosage units of Levothyroxine nearly doubled in price in November 2013 (based on National Average Drug Acquisition Cost ("NADAC") data), and continued to increase during the Class Period, with the respective dosage units each rising a total of between 185%-231% between November 14, 2013 and October 15, 2014.

6. Defendants' price increases were, for the most part, in lockstep. Levothyroxine prices remained at supra-competitive levels throughout the Class Period.

7. Defendants' price increases were against their economic self-interest. Levothyroxine is a commodity product. Therefore, absent a cartel, if any manufacturer increased the price of Levothyroxine, it would be expected that its competitors would not increase the price but would seek to sell more Levothyroxine to the first manufacturer's customers. Accordingly, it would not be in any manufacturer's unilateral self-interest to increase the price of the Levothyroxine it sold unless it had an agreement with the other manufacturers that they would do the same.

8. In 2013, there was no significant increase in the costs of making Levothyroxine, there was no significant decrease in supply, and there was no significant increase in demand.

Nonetheless, there were extraordinary increases by each of the Defendants in the prices they charged their customers for Levothyroxine. Such price increases in a commodity product for which there were no significant increases in costs or demand, or significant decrease in supply, would not have been in each Defendant's unilateral self-interest absent the existence of a cartel.

9. Defendants' dramatic and unexplained price increases have resulted in extensive scrutiny by and federal and state regulators, and the U.S. Congress.

10. On October 2, 2014, U.S. Senator Bernie Sanders and U.S. Congressman Elijah Cummings sent letters to several generic drug manufacturers, including Defendants Lannett and Mylan, asking for detailed information on their generic drug price increases.

11. On November 20, 2014, Senator Sanders's committee held a hearing entitled "Why Are Some Generic Drugs Skyrocketing In Price?" Various witnesses discussed the price increases for generic drugs. No chief executive of a generic drug manufacturer testified.

12. By November 3, 2014, the U.S. Department of Justice ("DOJ") opened a wide-ranging grand jury investigation into the marketing and pricing practices of generic drugs, and has caused grand jury subpoenas to be issued to several generic drug manufacturers, including Defendants Mylan, Sandoz and Lannett.

13. The DOJ is currently conducting a wide-ranging criminal investigation into collusion among generic drug companies. According to *Bloomberg News*, the investigation reportedly covers more than 12 companies and at least 24 drugs.

14. Defendants Lannett, Sandoz and Mylan have confirmed receipt of subpoenas from the DOJ.

15. On October 7, 2016, Mylan disclosed in a filing with the U.S. Securities and Exchange Commission ("SEC") that on September 8, 2016, the DOJ "subpoenaed a company

subsidiary, a senior executive and other employees about alleged price fixing and also executed multiple search warrants related to its probe." Mylan further disclosed that the DOJ is seeking "additional information relating to the marketing, pricing and sale of" several generic drugs, "and any communications with competitors about such products."

16. According to a *Bloomberg News* article, Sandoz has confirmed that it received a subpoena from the DOJ in March 2016, and stated that it believed the subpoena was related to "the industry-wide investigation into generic drug pricing in the U.S."[1]

17. On November 4, 2016, in its Form 10-Q for the quarter ended September 30, 2016, Lannett stated:

> In fiscal year 2015 and 2016, the Company and certain affiliated individuals each were served with a grand jury subpoena relating to a federal investigation of the generic pharmaceutical industry into possible violations of the Sherman Act. The subpoenas request corporate documents of the Company relating to corporate, financial and employee information, communications or correspondence with competitors regarding the sale of generic prescription medications and the marketing, sale, or pricing of certain products, generally for the period of 2005 through the dates of the subpoenas.

18. On December 15, 2016, several states' attorneys general, led by the State of Connecticut Office of Attorney General ("Connecticut AG"), filed a civil action for violations of the Sherman Antitrust Act ("Sherman Act") against Heritage Pharmaceuticals, Inc. and other sellers of Glyburide and Doxycycline Hyclate DR, including Defendant Mylan. The action filed by the attorneys general is styled *The State of Connecticut, et al., v. Aurobindo Pharma USA, Inc., Citron Pharma, LLC, Mylan Pharmaceuticals USA, Inc. and Teva Pharmaceuticals USA, Inc., Heritage Pharmaceuticals, Inc., and Mylan Pharmaceuticals, Inc.*, and is pending in U.S. District Court in Connecticut (16-cv-2056) (the "State AG Action").

[1] https://www.bloomberg.com/news/articles/2016-11-17/nypd-union-goes-after-drug-prices-amid-doj-pharma-investigation.

19. According to the State AG Action, the information developed through its investigation (which is still ongoing) uncovered evidence of a broad, well-coordinated and long-running series of schemes to fix the prices and allocate markets for a number of generic pharmaceuticals in the U.S. Although the State AG Action focuses on Glyburide and Doxycycline Hyclate DR, it alleges that the Plaintiff States have uncovered a wide-ranging series of conspiracies implicating numerous different drugs and competitors, including Defendant Mylan.

20. Plaintiff alleges that during the Class Period, Defendants combined, conspired and contracted to fix, raise, maintain and stabilize prices at which Levothyroxine would be sold in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. As a result of Defendants' unlawful conduct, Plaintiff and the other members of the Class paid artificially inflated prices that exceeded the amount they would have paid if a competitive market had determined prices for Levothyroxine.

II. PARTIES

21. Plaintiff FWK Holdings, L.L.C. is an Illinois limited liability company located in Glen Ellyn, Illinois. Plaintiff is the assignee of antitrust claims possessed by Frank W. Kerr Company ("Kerr") and brings this action as successor-in-interest to Kerr's claims arising from its purchase of Levothyroxine during the Class Period directly from one or more of the Defendants at artificially inflated prices.

22. Defendant Mylan Pharmaceuticals Inc. ("Mylan") is a West Virginia corporation with its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. During the Class Period, Mylan sold Levothyroxine in this District and throughout the United States. Mylan maintains an office in this District at 405 Lexington Avenue, NY, NY 10174.

23. Defendant Lannett Company, Inc. ("Lannett") is a Delaware corporation with its principal place of business at 9000 State Rd., Philadelphia, PA 19036. During the Class Period, Lannett sold Levothyroxine in this District and throughout the United States.

24. Defendant Sandoz, Inc., is a Colorado corporation with its principal place of business at 100 College Road West, Princeton, NJ 08540. Sandoz, Inc. is a wholly-owned subsidiary of Defendant Novartis AG. During the Class Period, Sandoz, Inc. sold Levothyroxine in this District and throughout the United States. Sandoz, Inc. manufactures products at locations in Hicksville and Melville, New York.

25. Defendant Novartis AG ("Novartis"), is a Swiss multinational pharmaceutical company based in Basel, Switzerland. During the Class Period, through Sandoz, Inc., Novartis sold Levothyroxine to customers in this District and other locations in the United States. Novartis maintains an office in this District at 230 Park Ave, 21st Floor, New York, NY 10169.

26. In this Complaint, Sandoz, Inc. and Novartis will be referred to collectively as "Sandoz."

27. Whenever in this Complaint reference is made to any act, deed, or transaction of any corporation, the allegation means that the corporation engaged in the act, deed, or transaction by or through its officers, directors, agents, employees, or representatives while they were actively engaged in the management, direction, control, or transaction of the corporation's business or affairs.

A. Agents and Co-Conspirators

28. Each Defendant acted as the principal of, or agent for, all other Defendants with respect to the acts, violations, and common course of conduct described in this Complaint.

29. Various other persons, firms, companies, and corporations not named as Defendants knowingly and willingly conspired with Defendants, and performed acts and made statements in furtherance of the conspiracy and the alleged anticompetitive conduct.

30. The wrongful acts alleged to have been done by any one Defendant or co-conspirator were authorized, ordered, or done by its directors, officers, managers, agents, employees, or representatives while actively engaged in the management, direction, or control of such Defendant's or co-conspirator's affairs.

III. JURISDICTION AND VENUE

31. Plaintiff brings this action to (i) recover treble damages, attorneys' fees, litigation expenses, and court costs, and (ii) secure injunctive relief for violations of Section 1 of the Sherman Act, 15 U.S.C. § 1, pursuant to Sections 4 and 16 of the Clayton Act of 1914 ("Clayton Act"), 15 U.S.C. §§ 15 and 26.

32. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1337(a), 1407, and 15 U.S.C. § 15.

33. Venue is proper in this District pursuant to 15 U.S.C. §§ 15(a), 22 and 28 U.S.C. §§ 1391(b), (c), and (d) because during the Class Period, Defendants resided, transacted business, were found, or had agents in this District, and a substantial portion of the alleged activity affecting interstate trade and commerce, discussed below, has been carried out in this District.

34. Defendants' conduct, as described in this Complaint, was within the flow of, was intended to, and did have a substantial effect on, the interstate commerce of the United States, including in this District.

35. This Court has personal jurisdiction over each Defendant, because each Defendant has transacted business, maintained substantial contacts, and/or committed overt acts in

furtherance of its illegal scheme and conspiracy throughout the United States and including in this District. The scheme and conspiracy have been directed at, and have had the intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States, including in this District.

IV. INTERSTATE TRADE AND COMMERCE

36. Defendants are the leading manufacturers and suppliers of Levothyroxine sold in the United States.

37. Levothyroxine is produced by or on behalf of Defendants or their affiliates in the United States and/or overseas.

38. During the Class Period, Defendants, directly or through one or more of their affiliates, sold Levothyroxine throughout the United States in a continuous and uninterrupted flow of interstate commerce, including through and into this District.

39. The activities of Defendants and their co-conspirators were within the flow of, intended to, and had a substantial effect on interstate commerce in the United States.

40. Defendants' and their co-conspirators' conduct, including the marketing and sale of Levothyroxine, took place within, has had, and was intended to have, a direct, substantial, and reasonably foreseeable anticompetitive effect upon interstate commerce within the United States.

41. The conspiracy alleged in this Complaint has directly and substantially affected interstate commerce in that Defendants deprived Plaintiff of the benefits of free and open competition in the purchase of Levothyroxine within the United States.

42. Defendants' agreement to inflate, fix, raise, maintain, or artificially stabilize prices of Levothyroxine, and their actual inflating, fixing, raising, maintaining, or artificially stabilizing Levothyroxine prices, were intended to have, and had, a direct, substantial, and reasonably

foreseeable effect on interstate commerce within the United States and on import trade and commerce with foreign nations.

V. FACTUAL ALLEGATIONS

A. Overview of the Generic Drug Market

1. Generic drugs should lead to lower prices

43. Brand name drugs are typically patented and the patent owner can charge a monopoly price. After the patent expires, generic drugs enter the market. Generic drugs typically provide consumers with a lower cost alternative to brand name drugs while providing the same treatment. Specifically:

> A generic drug is the same as a brand name drug in dosage, safety, strength, how it is taken, quality, performance, and intended use. Before approving a generic drug product, FDA requires many rigorous tests and procedures to assure that the generic drug can be substituted for the brand name drug. The FDA bases evaluations of substitutability, or "therapeutic equivalence," of generic drugs on scientific evaluations. By law, a generic drug product must contain the identical amounts of the same active ingredient(s) as the brand name product. Drug products evaluated as "therapeutically equivalent" can be expected to have equal effect and no difference when substituted for the brand name product.

FDA, Generic Drugs: Questions and Answers, *available at* http://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm.

44. Further, "[d]rug products classified as therapeutically equivalent can be substituted with the full expectation that the substituted product will produce the same clinical effect and safety profile as the prescribed product." *Id.*

45. Generic versions of brand name drugs are priced significantly below the brand versions. Because of the price differentials, and other institutional features of the pharmaceutical market, generic versions are liberally and substantially substituted for their brand counterparts. In every state, pharmacists are permitted (and, in some states, required) to substitute a generic product for a brand product unless the doctor has indicated that the prescription for the brand product must

be dispensed as written. States adopted substitution laws following the federal government's 1984 enactment of the Hatch-Waxman Act.

46. Prior to the conspiracy alleged herein, the FDA has recognized that "[g]eneric competition is associated with lower drug prices[.]" A Federal Trade Commission study reached the same conclusion finding that in a "mature generic market, generic prices are, on average, 85% lower than the pre-entry branded drug prices." Economic literature in the healthcare market further confirms that competition by generic products results in lower prices for consumers. In the period before generic entry, a brand drug commands 100% of the market share for that drug and the brand manufacturer can set the price without the impact of competitive market forces. Once the first generic enters the market, however, a brand drug rapidly loses sales, on average 90% within a year. As more generic manufacturers enter the market, prices for generic versions of a drug predictably will continue to decrease because of competition among the generic manufacturers, and the loss of sales volume by the brand drug to the corresponding generic accelerates as more generic options are available to purchasers.

47. A mature generic market, such as the market for Levothyroxine, has several generic competitors. Due to the fact that each generic is readily substitutable for another generic of the same brand drug, the products behave like commodities, with pricing being the main differentiating feature and the basis for competition among manufacturers.[2] Over time, generics' pricing nears the generic manufacturers' marginal costs.

48. Generic competition usually enables purchasers to purchase generic versions of the

[2] *See, e.g.*, FTC, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT, at 17 (Aug. 2011) ("[G]eneric drugs are commodity products marketed to wholesalers and drugstores primarily on the basis of price."); Congressional Budget Office, "How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry" (July 1998).

brand drug at a substantially lower price than the brand drug. Generic competition to a single blockbuster brand drug product can result in billions of dollars in savings to direct purchasers, consumers, insurers, local, state, and federal governments, and others. Indeed, one study found that the use of generic medicines saved the United States healthcare system $254 billion in 2014 alone, and $1.68 trillion between 2005 and 2014.

B. Consolidation of Generic Drug Market

49. The global market for generic pharmaceuticals has undergone substantial consolidation since 2005. For example, Teva Pharmaceutical Industries Ltd., acquired Ivax Corporation for $7.4 billion in 2006, Barr Laboratories for $7.4 billion in 2008, Ratiopharm—Germany's second largest generic drug producer—for $5 billion in 2010, and Allergan Generics in 2016 for $40.5 billion.

50. Other major transactions that occurred during the same time period include Watson Pharmaceuticals' $1.9 billion acquisition of Andrx Corporation in 2006; Daiichi Sankyo's purchase of a majority stake in Ranbaxy Laboratories, Ltd. in 2008; and Endo Pharmaceuticals' 2010 acquisition of Qualitest Pharmaceuticals for $1.2 billion.

51. In July 2012, Sandoz acquired Fougera Pharmaceuticals Inc. for $1.5 billion in cash.

52. In November 2015, Lannett acquired Kremers Urban Pharmaceuticals Inc. (KU), the U.S. specialty generic pharmaceuticals subsidiary of global biopharmaceuticals company UCB S.A. for $1.23 billion. In June 2015, Lannett acquired privately held, Silarx Pharmaceuticals, Inc., a manufacturer and marketer of generic pharmaceutical products.

53. As a result of consolidation, Defendants dominate the U.S. Levothyroxine market.

C. Opportunities for Collusion

54. The DOJ is reportedly looking closely at trade associations. According to an intelligence report from Policy and Regulatory Report, a source that was given inside information by someone with knowledge of the government's generic pricing investigation, the DOJ is looking closely "at trade associations as part of their investigation as having been one potential avenue for facilitating the collusion between salespeople at different generic producers."

55. Generic drug manufacturers attend various industry trade shows throughout the year, including those hosted by the GPhA, National Association of Chain Drug Stores, Healthcare Distribution Management Association (now the Healthcare Distribution Alliance), and Efficient Collaborative Retail Marketing.

56. At these various conferences and trade shows, representatives from Defendants have opportunities to interact with each other and discuss their respective businesses and customers. Attendant with many of these conferences and trade shows are organized recreational and social events, such as golf outings, lunches, cocktail parties, dinners, and other scheduled activities that provide further opportunity to meet with competitors outside of the traditional business setting. Of particular importance here, generic drug manufacturer representatives who attend these functions use these opportunities to discuss and share upcoming bids, specific generic drug markets, pricing strategies and pricing terms in their contracts with customers, among other competitively-sensitive information.

57. In short, these trade shows and customer conferences provide generic drug manufacturers with ample opportunity to meet, discuss, devise and implement a host of anticompetitive schemes that unreasonably restrain competition in the United States' market for generic drugs.

58. In addition to these frequent conferences and trade shows, representatives of generic drug manufacturers get together separately, in more limited groups, allowing them to further meet face-to-face with their competitors and discuss their business. A large number of generic drug manufacturers, including two of the Defendants, have offices in close proximity to one another in New Jersey, eastern Pennsylvania, or New York, giving them easier and more frequent opportunities to meet and collude. In fact, high-level executives of Defendants get together periodically for what at least some of them refer to as "industry dinners."

59. As a result of these various interactions, Defendants' sales and marketing executives are often acutely aware of their competition and, more importantly, each other's current and future business plans. This familiarity and opportunity often leads to agreements among competitors to fix prices or to allocate a given market so as to avoid competing with one another on price.

60. Defendants routinely communicate and share information with each other about bids and pricing strategy. This can include forwarding bid packages received from a customer (e.g., a Request for Proposal or "RFP") to a competitor, either on their own initiative, at the request of a competitor, or by contacting a competitor to request that the competitor share that type of information.

61. Defendants also share information regarding the terms of their contracts with customers, including various terms relating to pricing, price protection and rebates. Generic drug manufacturers use this information from their competitors to negotiate potentially better prices or terms with their customers, which could be to the ultimate detriment of consumers.

D. Levothyroxine Prices Soar

62. Before November 2013, the price of Levothyroxine was stable. Beginning in November 2013, Defendants caused the price of Levothyroxine to dramatically increase in unison. The increases were the result of an agreement among Defendants to increase pricing and restrain competition. Defendants met at least one or more times prior to implementing their price increases, including meetings at GPhA events.

63. The GPhA is the "leading trade association for generic drug manufacturers and distributors, manufacturers of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic industry." GPhA was formed in 2000 from the merger of three industry trade associations: GPhA, the National Association of Pharmaceutical Manufacturers, and the National Pharmaceutical Alliance.

64. According to GPhA's website, "GPhA member companies supply approximately 90 percent of the generic prescription drugs dispensed in the U.S. each year." GPhA states that, "[b]y becoming part of GPhA, you can participate in shaping the policies that govern the generic industry and help secure the future of this vital pharmaceutical market segment. In addition, GPhA provides valuable membership services, such as business networking opportunities, educational forums, access to lawmakers and regulators, and peer-to-peer connections."

65. Defendants each attended the GPhA Fall Technical Conference in Bethesda, Maryland on October 28-30, 2013, and the GPhA annual meeting in Orlando, Florida on February 19, 20 and 21, 2014.

66. These meetings, among other contacts among Defendants, provided Defendants with opportunities to collude, and on information and belief, at these meetings Defendants agreed to increase pricing for Levothyroxine.

67. Shortly after the October 2013 meeting, the average prices for Levothyroxine began to increase by extraordinary amounts. In November 2013 alone, according to NADAC data, each of the twelve available dosage units of Levothyroxine nearly doubled in price. In total, Levothyroxine tablets increased by the following amounts during the Class Period:

a. ***Levothyroxine 100 MCG Tablets.*** Between November 14, 2013 and October 15, 2014, average prices increased by 212%.

b. ***Levothyroxine 112 MCG Tablets.*** Between November 14, 2013 and October 15, 2014, average prices increased by 208%.

c. ***Levothyroxine 125 MCG Tablets.*** Between November 14, 2013 and October 15, 2014, average prices increased by 219%.

d. ***Levothyroxine 137 MCG Tablets.*** Between November 14, 2013 and October 15, 2014, average prices increased by 197%.

e. ***Levothyroxine 150 MCG Tablets.*** Between November 14, 2013 and October 15, 2014, average prices increased by 231%.

f. ***Levothyroxine 175 MCG Tablets.*** Between November 14, 2013 and October 15, 2014, average prices increased by 224%.

g. ***Levothyroxine 200 MCG Tablets.*** Between November 14, 2013 and October 15, 2014, average prices increased by 220%.

h. ***Levothyroxine 25 MCG Tablets.*** Between November 14, 2013 and October 15, 2014, average prices increased by 208%.

i. ***Levothyroxine 50 MCG Tablets.*** Between November 14, 2013 and October 15, 2014, average prices increased by 225%.

j. ***Levothyroxine 75 MCG Tablets.*** Between November 14, 2013 and October 15, 2014, average prices increased by 214%.

k. ***Levothyroxine 88 MCG Tablets.*** Between November 14, 2013 and October 15, 2014, average prices increased by 216%.

l. ***Levothyroxine 300 MCG Tablets.*** Between November 14, 2013 and October 15, 2014, average prices increased by 185%.

68. There were no reasonable justifications for this abrupt shift in pricing, as Defendants' price increases were not necessitated by increased manufacturing costs, or research and development costs. Likewise, there were no shortages of Levothyroxine in the United States.

69. Federal law requires drug manufacturers to report potential drug shortages to the FDA, the reasons therefor, and the expected duration of the shortage. No supply disruption was reported by Defendants with respect to Levothyroxine during the Class Period.

70. The abrupt shift in the pricing of Levothyroxine has had a devastating impact on customers. As noted in letters from members of Congress to generic drug manufacturers as part of a wide investigation into unexplained increases in generic drug prices:

> This dramatic increase in generic drug prices results in decreased access for patients. According to the National Community Pharmacists Association (NCPA), a 2013 member survey found that pharmacists across the country "have seen huge upswings in generic drug prices that are hurting patients and pharmacies ability to operate" and "77% of pharmacists reported 26 or more instances over the past six months of a large upswing in a generic drug's acquisition price." These price increases have a direct impact on patients' ability to purchase their needed medications. The NCPA survey found that "pharmacists reported patients declining their medication due to increased co-pays," and "84% of pharmacists said that the acquisition price/lagging reimbursement trend is having a 'very significant' impact on their ability to remain in business to continue serving patients.

71. Runaway generic drug price increases also have a detrimental impact on direct purchasers of the drugs:

> One factor that squeezed retailers' profit margins was the generic price inflation that roiled the pharmacy market, beginning in 2013 and extending through 2014 into 2015. **The sharp price hikes — particularly for single-source generics — increased pressure on pharmacy retailers, who were caught between rising acquisition costs and limits on how much they could raise their own prices at the pharmacy counter.** Compounding the squeeze: the frequent failure of MAC (maximum allowable cost)- and AMP (average manufacturer price)- based drug pricing models — and the payers that base their pharmacy reimbursements on them — to keep pace with the inflationary price spiral for some generics in their reimbursements to pharmacies for the medicines dispensed to their members.[3]

72. Similarly, a 2015 white paper published by Elsevier Clinical Solutions noted:

> High generic drug prices have had an adverse effect on almost everyone in the pharmaceutical supply chain. Consumers face higher co-pays and prices and health plans are dealing with higher drug spend. Physicians are finding the need to prescribe alternative drug therapies while dealing with angry patients. In some cases, consumers are declining their medications due to increased prices. **Many pharmacies are receiving inadequate reimbursements and can lose money when drugs must be purchased at rapidly rising prices but reimbursed at lower predetermined rates.**[4]

73. Another 2015 white paper examining generic drug pricing, published by Wolters Kluwer, explained:

> While the impact is being felt across the industry, small to mid-sized pharmacies can face notably greater challenges, as they do not have the resources, prescription volume, or affiliations with other purchasers that can empower them to bargain for discounts in a competitive marketplace. A survey conducted by the National Community Pharmacists Association (NCPA) revealed that pharmacy acquisition prices for many essential generic drugs have generally risen by between 600% and 1,000% in recent years. The same survey revealed that **84% of pharmacists at small or mid-sized pharmacies believed that increasing generic drug costs could result in unsustainable losses that would have a "very significant" impact on their ability to remain in business.**[5]

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[3] Drug Store News, "Generic Drug Report 2016," available at https://www.drugstorenews.com/sites/drugstorenews.Com/files/GenericReport_2016.pdf.

[4] "The Impact of Rising Generic Drug Prices on the U.S. Drug Supply Chain," at pp. 1-2, available at http://www.ncpa.co/pdf/elsevier_wp_genericdrug.pdf.

[5] Donald J. Dietz, RPh, MS, and Fred Hamilin, "Generic Drug Pricing: Understanding the Impact," available at http://www.wolterskluwercdi.com/documents/white-papers/ms-generic-pricing-info.pdf.

74. Levothyroxine was a major driver of revenue and profit for Defendants, meaning that their price-fixing scheme had the power to dramatically improve the companies' bottom lines. For example, an October 2013 Roth Capital Partners analyst report noted that "[t]he single largest revenue contributor for Lannett is the levothyroxine franchise, which is currently in an environment with limited generic competition." Indeed, the price-fixing scheme did result in increased profits for Lannett. For example, in Lannett's Q2 2014 Earnings Call on February 6, 2014 (just three months after the first sharp price increase), CFO Martin P. Galvan cited Levothyroxine as one of two "key products that are…driving our gross margin from a price increase perspective."

75. For Mylan, a much larger company than Lannett, Levothyroxine represented one of the company's top ten generic drugs by revenue throughout the Class Period. According to analyst estimates published by Susquehanna Financial Group, LLLP, Mylan's North America revenues from Levothyroxine sales increased from $88.7 million in 2012, to $150 million in 2013, to $200 million in 2014, to $300 million in 2015, with $280 million projected for 2016.

76. In Mylan's Q2 2015 Earnings Call on August 6, 2015, John D. Sheehan – Mylan's Executive VP, Chief Financial & Accounting Officer – cited "increased margins on existing [generic] products in North America," and noted "positive pricing in the North America," even as Mylan increased "mid-single-digit price declines in Europe… and low-single-digit price in the rest of world."

VI. THE LEVOTHYROXINE MARKET IS HIGHLY SUSCEPTIBLE TO COLLUSION

77. Factors showing that the Levothyroxine market is susceptible to collusion are present in this case.

78. **High Degree of Industry Concentration**: A concentrated market is more susceptible to collusion and other anticompetitive practices. The Levothyroxine market is highly

concentrated and is dominated primarily by only three companies. Therefore, elaborate communications, quick to be detected, would not have been necessary to enable pricing to be coordinated.

79. **High Barriers to Entry**: Costs of manufacture, intellectual property, and expenses related to regulatory oversight are barriers to entry. Barriers to entry increase a market's susceptibility to a coordinated effort to maintain supracompetitive prices because it is difficult for new suppliers to enter the market and destabilize coordinated supracompetitive prices.

80. As the dominant players in the Levothyroxine market, Defendants were able to fix, raise, and maintain their prices for Levothyroxine without competitive threats from rival generic drug manufacturers.

81. **Lack of Substitutes**: Many patients are unable to substitute other medications for Levothyroxine. In some cases, Levothyroxine is the only effective treatment for thyroid hormone deficiency.

82. **Demand Inelasticity**: "Elasticity" is a term used to describe the sensitivity of supply and demand to changes in one or the other. For example, demand is said to be "inelastic" if an increase in the price of a product results in only a small decline, if any, in the quantity sold of that product. In other words, customers have nowhere to turn for alternative, cheaper products of similar quality, and so continue to purchase the product despite the price increase.

83. For a cartel to profit from raising prices above competitive levels, demand must be relatively inelastic at competitive prices. Otherwise, increased prices would result in declining sales, revenues, and profits as customers purchased substitute products or declined to buy altogether. Inelastic demand is a market characteristic that facilitates collusion, allowing producers to raise their prices without triggering customer substitution and lost sales revenue.

84. Demand for Levotyhroxine is highly inelastic because it is a unique product for which there is no reasonable substitute. Levothyroxine is a necessary treatment for millions of patients for which no substitutes are available. Levothyroxine is thus particularly susceptible to collusive price fixing as price increases will not result in such a loss of sales as to reduce profits, but instead will result in more profits for cartel members.

85. **High Degree of Interchangeability**: Levothyroxine is a commodity product. Therefore, Defendants' products are interchangeable, as they contain the same chemical compounds made from the same raw materials and are therapeutically equivalent. This characteristic facilitates collusion because cartel members can more easily monitor and detect deviations from a price-fixing agreement. In addition, because these are commodity products, all Defendants had to raise prices for the cartel to work. Indeed, it was against a Defendant's individual economic interest to raise prices since the other Defendants could have priced below that Defendant's price and taken substantial market share.

86. **Opportunities for Contact and Communication Among Competitors**: Defendants are members of the trade association GPhA, and attend other industry events and meetings, which provides opportunities to communicate. Defendants' representatives regularly attended meetings of GPhA, including the October 2013 meeting and meetings of other trade associations during the Class Period. Indeed, the DOJ is reportedly analyzing trade associations like GPhA as a potential avenue for facilitating collusion between different generic drug manufacturers as part of its years-long investigation into anticompetitive pricing activities among them.

VII. THE DEFENDANTS ACTED AGAINST THEIR UNILATERAL SELF-INTEREST ABSENT A CARTEL

87. Levothyroxine is a commodity product. Therefore, absent a cartel, if any manufacturer increased the price of Levothyroxine, it would be expected that its competitors would not increase the price but would seek to sell more Levothyroxine to the first manufacturer's customers. Accordingly, it would not be in any manufacturer's unilateral self-interest to increase the price of the Levothyroxine it sold unless it had an agreement with the other manufacturers that they would do the same.

88. During the Class Period, there was no significant increase in the costs of making Levothyroxine and no significant increase in demand. Nonetheless, there were extraordinary increases by each of the Defendants in the prices they charged their customers for Levothyroxine. Such price increases in a commodity product for which there were no significant increases in costs or demand would not have been in each Defendant's unilateral self-interest absent the existence of a cartel.

VIII. CLASS ACTION ALLEGATIONS

89. Pursuant to Federal Rules of Civil Procedure 23(a), (b)(2) and (b)(3), Plaintiff brings this action on behalf of a Class defined as follows:

> All persons or entities that directly purchased Levothyroxine from Defendants in the United States and its territories and possessions at any time during the Class Period (November 21, 2013 to the present). Excluded from the Class are Defendants and their officers, directors, management, employees, subsidiaries, or affiliates, and all federal governmental entities.

90. Members of the Class are so numerous that joinder is impracticable. Plaintiff believes the Class Members are numerous and widely dispersed throughout the United States. Further, the Class is readily identifiable from information and records maintained by Defendants.

91. Plaintiff's claims are typical of the claims of the members of the Class. Plaintiff's interests are not antagonistic to the claims of the other Class Members, and there are no material conflicts with any other member of the Class that would make class certification inappropriate. Plaintiff and all members of the Class were damaged by the same wrongful conduct of Defendants.

92. Plaintiff will fairly and adequately protect and represent the interests of the Class. The interests of the Plaintiff are coincident with, and not antagonistic to, those of the Class.

93. Plaintiff is represented by counsel who are experienced and competent in the prosecution of class action litigation, and who have particular experience with class action litigation involving alleged violations of antitrust law in the pharmaceutical industry.

94. Questions of law and fact common to the members of the Class predominate over questions that may affect only individual Class Members because Defendants have acted on grounds generally applicable to the entire Class, thereby determining damages with respect to the Class as a whole is appropriate. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

95. The common legal and factual questions, which do not vary from Class Member to Class Member and which may be determined without reference to individual circumstances of any Class Member, include, but are not limited to, the following:

a. Whether Defendants and their co-conspirators engaged in a contract, combination, or conspiracy to eliminate competition and thereby artificially increase the prices of Levothyroxine in the United States;

b. The duration and extent of the alleged contract, combination, or conspiracy;

c. Whether Defendants and their co-conspirators were participants in the contract, combination, or conspiracy alleged herein;

d. The effect of the contract, combination, or conspiracy on the prices of Levothyroxine in the United States during the Class Period;

e. Whether Defendants' conduct caused supracompetitive prices for Levothyroxine;

f. Whether, and to what extent, the conduct of Defendants and their co-conspirators caused injury to Plaintiff and other members of the Class; and

g. Whether the alleged contract, combination, or conspiracy violated Section 1 of the Sherman Act, 15 U.S.C. § 1.

96. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated persons or entities to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

97. Plaintiff knows of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

IX. ANTITRUST INJURY

98. During the Class Period, Plaintiff and Class Members directly purchased Levothyroxine from Defendants. As a result of the Defendants' anticompetitive conduct, Plaintiff and Class Members paid more for Levothyroxine than they would have and thus suffered overcharges. This is a cognizable antitrust injury and constitutes harm to competition under the federal antitrust laws.

99. Because Defendants' unlawful conduct has successfully eliminated competition, Plaintiff and Class Members have sustained, and continue to sustain, significant overcharges in the form of artificially inflated prices paid to Defendants. The full amount of such overcharges will be calculated after discovery and upon proof at trial.

100. Defendants' misconduct reduced competition in the sale of Levothyroxine, reduced choice for purchasers, and caused injury to purchasers.

101. Defendants' anticompetitive conduct is ongoing, and as a result Plaintiff and the Class continue to pay supracompetitive prices for Levothyroxine.

X. VIOLATION OF THE SHERMAN ACT § 1

102. Defendants and their co-conspirators entered into, and engaged in, a contract, combination, or conspiracy in unreasonable restraint of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

103. Defendants' anticompetitive acts were intentional, were directed at the sales of Levothyroxine in the United States, and had a substantial and foreseeable effect on interstate commerce by raising and fixing Levothyroxine prices throughout the United States.

104. The contract, combination, or conspiracy had the following direct, substantial, and reasonably foreseeable effects upon commerce in the United States:

a. Prices charged to, and paid by, Plaintiff for Levothyroxine were artificially raised, fixed, maintained, or stabilized at supra-competitive levels;

b. Plaintiff was deprived of the benefits of free, open, and unrestricted competition in the sale of Levothyroxine in the United States market; and

c. Competition in establishing the prices paid for Levothyroxine was unlawfully restrained, suppressed, or eliminated.

105. Defendants' and their co-conspirators' anticompetitive activities directly and proximately caused injury to Plaintiff in the United States.

106. As a direct and proximate result of Defendants' unlawful conduct, Plaintiff paid artificially inflated prices for Levothyroxine.

107. As a direct and proximate result of Defendants' unlawful conduct, Plaintiff was damaged in its business or property by paying prices for Levothyroxine that were higher than they would have been but for Defendants' unlawful conduct, which has resulted in an amount of ascertainable overcharges to be established at trial.

DEMAND FOR RELIEF

WHEREFORE, Plaintiff and Class Members respectfully demand the relief as set forth below:

A. Certification of the action as a Class Action pursuant to Federal Rule of Civil Procedure 23, and appointment of Plaintiff as Class Representative and its counsel of record as Class Counsel;

B. That acts alleged herein be adjudged and decreed to be unlawful restraints of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1;

C. Permanent injunctive relief that enjoins Defendants from violating the antitrust laws and requires them to take affirmative steps to dissipate the effects of the violations;

D. A judgment against Defendants, jointly and severally, for the damages sustained by Plaintiff and the Class defined herein, and for any additional damages, penalties, and other monetary relief provided by applicable law, including treble damages;

E. By awarding Plaintiff and Class Members pre-judgment and post-judgment interest as provided by law, and that such interest be awarded at the highest legal rate from and after the date of service of the Complaint in this action;

F. The costs of this suit, including reasonable attorney fees; and

G. Such other and further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff, on behalf of itself and all others similarly situated, hereby requests a jury trial, pursuant to Federal Rule of Civil Procedure 38, on any and all claims so triable.

Dated: December 23, 2016

Respectfully submitted,

KAPLAN FOX & KILSHEIMER LLP

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